

PH7442 NP
10/776828Interview Summary

Applicants appreciate the productive telephone interview conducted with the Examiner on June 12, 2006. The primary discussion involved the obviousness rejection of the present compound claims over the disclosure of Ewing, et.al.

In the office action of April 26, 2006, the Examiner continued to contend that Ewing et al. suggested Applicants' compounds by "structural similarity" via an analysis of the Ewing genus, as discussed further below.

Applicants disagreed, pointing out that the compounds suggested by Ewing et al. are not structurally similar. By both preference and example Ewing actually teaches away from Applicants particularly substituted five-membered (thio)lactams. (See "Preferred Embodiments" section in Ewing, beginning page 18 and "Examples" beginning on 78) As detailed further in the "Remarks" section below, Applicants believe that the most similar Ewing preferred embodiment teaches six-membered nitrogen-containing ring cores, which may be lactams, that can be substituted by the groups L_1Cy_1 and L_2Cy_2 , neither of which can be the (heteroaryl)(R_9)N- ligand of Applicants' compounds. Likewise, Ewing's examples describe only six-membered nitrogen containing core rings that are not substituted by a heteroaryl-N substituent, let alone by both a (heteroaryl)(R_9)N- ligand and Applicants' particularly substituted cyclohexyl group. Accordingly, there is no suggestion in Ewing et al., by either preference or example, that would provide motivation to one of skill in the art to obtain Applicants' claimed compounds.

PH7442 NP
10/776828

The Examiner understood this analysis and agreed to
withdrawn the rejection of the compound claims under 35
U.S.C. 103(a) over Ewing et al.

PH7442 NP
10/776828**REMARKS**

Reconsideration and reexamination is respectfully requested.

Amendments

Withdrawn claims 23 and 24 have been canceled and dependent claim 25 have been rewritten to incorporate the limitations of the canceled claims. Claims 25 and 29 have also been amended to delete the limitation "cancer" and to correct minor typographical errors. No new matter has been added by the present amendments nor has the scope of the claims been broadened thereby. Applicants reserve the right to file continuing and/or divisional applications on unclaimed subject matter, including the unclaimed subject matter of the amended and canceled claims.

Rejection under 35 U.S.C. 103

In the last office action, the Examiner continued to contend that Ewing et al. allegedly suggested Applicants compounds because the broad Ewing Markush genus included the possibility of a 5-membered lactam that may be N-substituted with a cycloalkyl group (See April 26, 2006 office action pages 3-4). This contention was coupled with the observation that the Ewing definition of "cycloalkyl" included cyclohexyl as a "representative group" having amino and amidino preferred substituents. Applicants respectfully traverse.

According to the MPEP, 2144.08, "[w]hen evaluating the scope of a claim, every limitation in the claim must be considered. See, e.g., In re Ochiai, 71 F.3d 1565, 1572, 37 USPQ2d 1127, 1133 (Fed. Cir. 1995). However, the claimed invention may not be dissected into discrete elements to be analyzed in isolation, but must be considered as a whole. See, e.g., W.L. Gore & Assoc.,

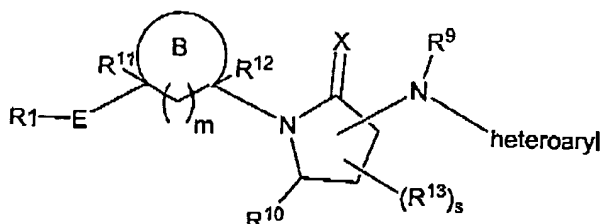
PH7442 NP
10/776828

Inc. v. Garlock, Inc., 721 F.2d 1540, 1548, 220 USPQ 303, 309 (Fed. Cir. 1983);" etc.

Moreover, "the fact that a claimed species or subgenus is encompassed by a prior art genus is not sufficient by itself to establish a prima facie case of obviousness. *In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994) ("The fact that a claimed compound may be encompassed by a disclosed generic formula does not by itself render that compound obvious.")". The *Baird* court goes on to hold that the generic formula of the prior art does not suggest the species where a prior art reference suggested that other compounds were preferred. *Id.*

Applicants believe the Examiner has mistakenly analyzed the broad Ewing genus in combination with a single variable definition in order to construct Ewing's alleged "suggestion" of Applicant's compounds. According to the instruction in MPEP 2144,08, this amounts to an improper finding of "suggestion" in the broad genus via "hindsight" construction without taking all the limitations of the claims into account. Nor does the Examiner considering the Applicants' claimed compound as a whole by such an analysis. As held in *Baird*, Applicants believe that Ewing's preferred compounds (and examples) are structurally dissimilar and actually teach away from Applicants claimed compounds. (See "Preferred Embodiments" section in Ewing, beginning page 18 and "Examples" beginning on 78)

For the purposes of comparison only, a summarized description of applicant's claimed compounds follows:

PH7442 NP
10/776828

where B is cyclohexyl; X is O or S; m is 0 or 1; and R^1 , and $R^9 - R^{13}$ are as described in present claim 1.

Accordingly, Applicants' invention can be broadly described as a five-membered lactam (or thiolactam) core that is necessarily N-substituted by a particularly substituted cyclohexyl group (corresponds to genus definition of L_2Cy_2 in Ewing) and a (heteroaryl)(R_9)N-ligand (corresponds to genus definition of L_1Cy_1 in Ewing).

At most, Ewing's preferred embodiments teach six-membered nitrogen containing ring cores, which may be lactams, that are substituted by the groups L_1Cy_1 and L_2Cy_2 . (See page 54, line 20 and various preferred embodiments on page 54 and 55 where R_1 , R_{1a} , R_2 , R_{2a} , R_3 , R_{3a} , R_4 , and R_{4a} are all present). More particularly, while L_2 can be absent and Cy_2 can be a cycloalkyl group, L_1Cy_1 preferred groups are as follows: $-S(O)_p-Cy_1$, $-C(X)Y-Cy_1$, or $L_3Q-L_4-Q'-L_5-Cy_1$, $-L_3Q-L_4Q'-L_5-$, $-L_3-Q-L_4-Q'-L_5-Cy_1$, (page 55, lines 8, 29, 31 and page 56, lines 1-11). None of the aforementioned definitions of L_1Cy_1 describe (heteroaryl)(R_9)N-ligand. Accordingly, Ewing does not suggest a five-membered lactam core, let alone any lactam substituted by a (heteroaryl)(R_9)N-ligand. Finally, if one considers Applicants' claimed compounds as a whole, Ewing certainly does not suggest a 5-membered (thio)lactam that is N-substituted with a particularly

PH7442 NP
10/776828


substituted cyclohexyl group and a (heteroaryl) (R₉)N-ligand. Accordingly, Ewing's preferred embodiments and examples actually teach away from Applicants inventive compounds providing no motivation or suggestion other than the broad Ewing genus to obtain Applicants' claimed compounds. Accordingly, withdrawal of the rejection under 35 U.S.C. 103(a) over Ewing is respectfully requested.

Upon a finding that claims 1 and/or 7 are allowable, rejoinder of the respective dependent method-of-treatment claims (claims 25, 26, 29, and 38) is requested.

The application is believed to be in condition for acceptance and notification thereof is respectfully requested. The Examiner is welcomed to call Applicants' representative if he feels a telephone interview would further the prosecution of this application.

Respectfully submitted,

Bristol-Myers Squibb Company
Patent Department
P.O. Box 4000
Princeton, NJ 08543-4000
Date: June 22, 2006


Laurelee A. Duncan
Attorney for Applicant
Reg. No. 44,096
Phone: 609-252-5323